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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,005	12/06/2004	Antonio Polato	66434-019	8747
25269	7590	09/05/2008	EXAMINER	
DYKEMA GOSSETT PLLC			LEFF, STEVEN N	
FRANKLIN SQUARE, THIRD FLOOR WEST				
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WASHINGTON, DC 20005			1794	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,005	POLATO ET AL.	
	Examiner	Art Unit	
	STEVEN LEFF	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 May 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-24 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/6/04, 5/21/08</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Election/Restrictions

Claims 1-13, and 19-24 directed to a method of treating an unpackaged biological fluid, and claims 14-18 directed to an apparatus for treating an unpackaged biological fluid, previously resulting in a restriction requirement, are hereby rejoined and fully examined for patentability.

The restriction requirement of inventions I and II as set forth in the Office action mailed on 3/24/08 is hereby withdrawn. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - Claims 1 and 14 are rejected specifically due to the phrases “close to a storage temperature” and “close to said storage temperature” in steps c) and f) are rejected, as they are relative phrase, which renders the claim indefinite. It is unclear as to what is encompassed by the phrases, it is unclear as to what degree of difference is encompassed by this phrase, if not a “storage temperature” since frozen temperatures, cool temperatures and room temperatures are all “storage temperatures” of biological liquids.
 - Claim 5 is rejected due to the phrase “wherein said heat treatment step b) comprises sterilization and the preheating temperature of the fatty fraction is between 140°C and 150°C” as it appears to conflict with independent claim 1 due to claim 1 step b) being

with respect to the second fraction of the fraction which has a lower fat content, however claim 5 teaches that step b) is with respect to the fatty fraction and thus it is unclear if the preheating temperature of between 140°C and 150°C is with respect to the first fraction, the second fraction, or both.

- Claim 14 is rejected due to the phrases “means for” as it is unclear if these are to be the same “means for” as taught by independent claim 1, or with respect to different “means for” altogether.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holm et al. (4876100) in view of Polato et al. (5976592).

Holm et al. teach a method for treating an unpackaged biological liquid, having a microbacterial and spore content and an initial concentration of fatty matter (col. 3 lines 36-56). More specifically Holm et al. teach separating said biological liquid into a first fraction having a higher concentration of fatty matter compared to said initial concentration and a second fraction having a lower concentration of fatty matter compared to said initial concentration using a separating means (col. 3 lines 36-56), heat treating said second fraction using said heating means (col. 6 lines 36-39), preheating said first fraction to a predetermined temperature using said preheating

means (col. 5 lines 17-29), sterilizing the first fraction (col. 8 lines 11-13), and mixing said first and second fractions so that the first fraction and the second fraction reconstitute a biological liquid using a mixing means (col. 5 lines 36-37). Holm et al. further teach the system is of continuous flow (col. 5 lines 27-28), cooling the first and second fractions individually prior to their recombining (col. 8 lines 17-18 as it is noted that the need and use of the regenerative heater inherently implies that the fractions underwent some degree of cooling), that the first fraction contains substantially all of the fatty matter of the biological liquid (col. 7 lines 61-65), that the first fraction is about 10% by weight of the biological fluid (col. 8 lines 7-8) a means for mixing (col. 8 lines 15-17) and a pasteurization temperature of 77C (col. 8 lines 20-21).

However Holm et al. is silent with respect to a cooling means, irradiating said preheated first fraction with electromagnetic radiation for a predetermined time using an irradiating mean wherein said electromagnetic radiation is in the radio-frequency range which is less than 1GHz, that the irradiation time is 1-5 seconds, that the preheating temperature of the fatty fraction is between 140°C and 150°C, that the heat treatment step b) is pasteurization and the preheating temperature is between 70°C and 75°C, or that the heating temperature is between 80C and 100C, or 85C and 95C and the preheating temperature is between 90C and 125C or 115C and 125C, that the cooling time of the first fraction is between 2 and 5 seconds.

Polato teaches a method and apparatus for the continuous sterilization of non-packaged liquid, and particularly milk and its byproducts (abstract). More specifically Polato teaches a cooling means (col. 4 lines 53-61, col. 6 lines 30-31), irradiating said preheated milk with electromagnetic radiation for a predetermined time using an irradiating mean wherein said electromagnetic radiation is in the radio-frequency range (col. 4 line 22) which is less than 1GHz (col. 4 lines 23-28, col. 6 lines 12-13). Polato continues by teaching that the irradiation time is 1-5 seconds (col. 4 lines 11-13), that the preheating temperature of the milk is 140°C (col. 4 line 4), that the heat treatment step b) is pasteurization (col. 4 lines 5-13) and that the heating temperature is at a maximum of 165C, the preheating temperature is between 90C and 125C or 115C and 125C (col. 4 lines 1-4).

Although Holm et al. does not teach the specific type of sterilization apparatus used, Holm et al. does generically teach a sterilization unit (col. 6 lines 63-65) for

sterilizing a fractionated milk product. Thus since Polato teaches a method and apparatus for the continuous sterilization of non-packaged liquid, and particularly milk and its byproducts (abstract), where the sterilization is specifically an irradiating means, one of one of ordinary skill in the art would have been motivated to combine the teachings of Holm et al. and Polato since Holm et al. teaches the desire to sterilize a fractionated milk product to remove bacteria (abstract) and since Polato teaches specifically sterilizing milk for its art recognized and applicant's intended purpose providing specific sterilization parameters which are "according to the composition of the product and to its bacterial concentration" (col. 4 lines 25-27).

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to teach the specific use of an irradiating means for sterilizing milk since MPEP 2144.07 states that the selection of a known process based on its suitability for its intended use supports a *prima facie* obviousness determination, where in the instant case Polato specifically teaches such with respect to applicant's specific product.

In addition, although Holm et al. is silent with respect to a cooling means, irradiating said preheated first fraction with electromagnetic radiation for a predetermined time using an irradiating mean wherein said electromagnetic radiation is in the radio-frequency range which is less than 1GHz, that the irradiation time is 1-5 seconds, that the preheating temperature of the fatty fraction is between 140°C and 150°C, that the heat treatment step b) is pasteurization and the preheating temperature is between 70°C and 75°C, or that the heating temperature is between 80C and 100C, or 85C and 95C and the preheating temperature is between 90C and 125C or 115C and 125C, that the cooling time of the first fraction is between 2 and 5 seconds, Holm et al. does recognize the need to sterilize milk.

Therefore since the specific temperature of the irradiating source, the higher the bacterial concentration, the kind of food, and the composition of the product proportionally effect the other variable needed to maintain the food in a specific temperature range which is required to achieve the desired inhibition of the population of bacteria, and since the only difference between the prior art and the claims was a recitation of specific times and treating temperatures with respect to the treating material, one of one of ordinary skill in the art would have been motivated to combine the

teachings of Holm et al. and Polato in order to provide optimize sterilization taking into consideration the operational parameters.

Therefore since Holm et al. teaches the claimed method and Polato et al. specifically teach irradiating said preheated milk with electromagnetic radiation for a predetermined time using an irradiating mean wherein said electromagnetic radiation is in the radio-frequency range (col. 4 line 22) which is less than 1GHz (col. 4 lines 23-28, col. 6 lines 12-13). Polato continues by teaching that the irradiation time is 1-5 seconds (col. 4 lines 11-13), that the preheating temperature of the milk is 140°C (col. 4 line 4), that the heat treatment step b) is pasteurization (col. 4 lines 5-13) and that the heating temperature is at a maximum of 165C, the preheating temperature is between 90C and 125C or 115C and 125C (col. 4 lines 1-4), one of ordinary skill in the art would not expect the method of the instant claims to perform differently than the prior art methods, thus the claimed method is not patentably distinct from the prior art method (See MPEP 2144.04 IV A). "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation," (see MPEP 2144.05 IIA), as the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages" (see MPEP 2144.05 IIA) for optimizing and achieving the desired amount of bacteria reduction with regard to the population of micro-organisms, with respect to a specific food item and a specific composition, in order to reduce the duration of the high temperature treatment thus preventing the destruction and alteration of the active principals and of the organic and organoleptic properties of the product as is desired by Polato (col. 3 lines 33-39).

Therefore it would have been obvious to one of ordinary skill in the art to teach specific rates, and temperatures with respect to milk since all the claimed elements were known in the prior art and one skilled in the art could have substituted the optimum or workable ranges with no change in their respective functions, thus yielding predictable results to one of ordinary skill in the art at the time of the invention. It would have further been obvious since combining the two methods, each of which is taught by the prior art to be useful for the same purpose of providing a sterilized milk product, flows logically from their having been individually taught in the prior art (see MPEP 2144.06),

since MPEP 2144.07 states that the selection of a known process based on its suitability for its intended use supports a *prima facie* obviousness determination.

With respect specifically to the preheating temperatures, Holm et al recognizes the need to preheat the milk product (col. 7 lines 45-47), and since Polato et al. teaches preheating to a temperature of between 90C and 140C (col. 5 lines 16-17), for its art recognized purpose of reducing the duration of the high temperature treatment thus preventing the destruction and alteration of the active principals and of the organic and organoleptic properties of the product, one of ordinary skill in the art would not expect the method of the instant claims to perform differently than the prior art methods, thus the claimed method is not patentably distinct from the prior art method (See MPEP 2144.04 IV A). "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation," (see MPEP 2144.05 IIA), as the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages" (see MPEP 2144.05 IIA) to achieve the desired amount of bacteria reduction with regard to the population of micro-organisms with respect to a specific food item and a specific composition.

With respect to the specific cooling time of the first fraction being between 2 and 5 seconds, although Holm et al. does not teach the specific cooling time, Holm et al. does teach cooling to packing temperature (col. 8 lines 22-23) where it is noted that the specific cooling temperature directly affects the time required to cool the milk to a specific cooled temperature. For example, one liter of milk will cool when exposed to 0C temperatures at a much quicker rate than at a cooling temperature of 15C. Therefore since the time of cooling to a specific temperature is dependent upon the specific temperature of the product, and the amount of the product to be cooled to a specific cooled temperature and since the cooling temperature is undefined, it would have been obvious to teach specific cooling times of between 2 and 5 seconds or more specifically about 3 seconds, since the general conditions of a claim are disclosed in the prior art and it is not inventive to discover the optimum or workable ranges by routine experimentation," (see MPEP 2144.05 IIA), as the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of

percentages" (see MPEP 2144.05 IIA) to achieve the desired cooling temperature where the type and specific cooling means temperature is undefined.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Leff whose telephone number is (571) 272-6527. The examiner can normally be reached on Mon-Fri 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached at (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Drew E Becker/
Primary Examiner, Art Unit 1794

/S. L./
Examiner, Art Unit 1794